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Guidance for Reporting SARS-CoV-2 Sequencing Results

Updated Mar. 21, 2022

Summary of Recent Changes

Updates as of March 21, 2022

- Updates to the examples for variant reporting when using just text.
- Updates to include information on finding the latest SNOMED CT coding of variant lineages for states that prefer codified reporting.
- Addition of 100157-7 as the preferred LOINC code to report sequencing results for the lineage designation.

View Previous Updates

Key Points

- CDC requests laboratories that are sequencing SARS-CoV-2 positive specimens to report those data to state, local, tribal, or territorial public health departments.
- The technical guidance provides detailed instructions and examples for how to report SARS-CoV-2 sequencing results to state, local, tribal, or territorial public health departments.

> It is critically important for the nation's COVID-19 pandemic response to understand the genetic diversity, spread, and evolution of SARS-CoV-2, including variant viruses.

Regulatory Position on Reporting Sequencing Results to Public Health Departments

The Centers for Medicare and Medicaid Services (CMS) published information that allows both non Clinical Laboratory Improvement Amendments (CLIA) and CLIA-certified facilities that perform SARS-CoV-2 genetic sequencing on identified specimens to report patient-specific results to state, local, tribal, or territorial public health departments. Any sequencing data can be reported to public health.

Laboratories should only report results to patients or providers when the methods used to perform the sequencing have met CLIA requirements for establishing performance specifications and have received Emergency Use Authorization (EUA) from the U.S. Food and Drug Administration (FDA). If the SARS-CoV-2 genetic sequencing result is reported to the ordering provider, reported to the patient, or appears in the patient record — and is intended to be used for the purposes of a person's diagnosis, prevention, treatment, or health assessment — then the test must be performed in a CLIA-certified laboratory or facility and must comply with all applicable CLIA and FDA regulations.

In a November 15, 2021 update to the Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised), FDA now requires COVID-19 diagnostic test developers to submit an EUA request for review and authorization prior to offering a test for diagnostic use or reporting test results to a healthcare provider, patient, or medical record. If a test was in use prior to November 15, 2021, and an EUA request was submitted to FDA within 60 days of the date of this policy update, FDA does not intend to object to the continued offering of a COVID-19 diagnostic test without EUA while FDA reviews the EUA request.

In both scenarios, CDC strongly recommends and requests that laboratories send sequencing results to state, local, tribal, or territorial public health departments.

How to Report SARS-CoV-2 Sequencing Results to Public Health Departments

This guidance outlines the process for adding a SARS-CoV-2 genetic sequencing result to an existing electronic laboratory report to provide that information to the state, local, tribal, or territorial health departments. SARS-CoV-2 sequencing results should be reported as a follow-up to the original positive viral test result and reported to the same public health department. The electronic reporting of the sequencing data should include all the original patient demographic data, along with both the viral test report content and the second ordered test with viral genetic lineage identified. Laboratories and facilities that have SARS-CoV-2 positive specimens and intend to report SARS-CoV-2 lineages, including variants, should upload sequence data to a public database (e.g., GISAID, NCBI Gene Bank)

Technical Guidance for Reporting Sequencing Results to Public Health Departments

The table below provides detailed guidance on reporting SARS-CoV-2 sequencing results to state, local, tribal, or territorial public health departments and includes examples for packaging data elements. This technical guidance is **subject to change as new information becomes available about the impact of SARS-CoV-2 evolution on public health**. For simplicity, only the fields needing more guidance in the additional observations for the variant lineage and the ID for the sequence sample are highlighted here. Other data elements normally part of each Observation/Result Segment (OBX), such as the result date, still need to be packaged as well.

Test Result (Performed and Values)

Required Reporting
Federal / CDC / HHS
State / Local / Tribal / Territorial PHD

Requested Reporting
Ordering Provider / EHR*

Technical Specifications
Must use harmonized LOINC codes, when available

Notes
SARS-CoV-2 pango lineage identified through sequencing from the original specimen

Example
LOINC: Preferred =100157-7 SARS-CoV-2 (COVID-19) lineage [Type] in Specimen by Sequencing

Allowable = 96741-4:

SARS-CoV-2 (COVID-19) variant [Type] in Specimen by Sequencing

or

96895-8:
SARS-CoV-2 (COVID-19) lineage [Identifier] in Specimen by Molecular genetics method
Example answers:
SARS-CoV-2 B.1.1.7 lineage OR B.1.1.7
SARS-CoV-2 B.1.351 lineage OR B.1.351
SARS-CoV-2 P.1 lineage OR P.1
SARS-CoV-2 B.1.429 lineage OR B.1.429
SARS-CoV-2 B.1.526 lineage OR B.1.526
SARS-CoV-2 B.1.427 lineage OR B.1.427
SARS-CoV-2 P.2 lineage OR P.2

When reporting to states that require SNOMED CT codes, please check for the latest available codes here: COVID-19 Resource Library

HL7 Field
OBX-3
OBX-2
OBX-5

Test Result Date

Required Reporting
Federal / CDC / HHS
State / Local / Tribal / Territorial PHD

Requested Reporting
Ordering Provider / EHR*

Technical Specifications
YYYY[MM[DD]]

Notes
Date the test result was obtained

Example
Example: 20200716

HL7 Field
OBX-19.1

Device Identifier

Required Reporting
Federal / CDC / HHS
State / Local / Tribal / Territorial PHD

Requested Reporting
Ordering Provider / EHR*

Technical Specifications
Must use harmonized Device Identifiers, when available. The DI is contained within the UDI, created by manufacturer

Notes
Manufacturer requests UDI issuance , then provides DI, or pull from GUDID database If DIs unavailable: Use the Unique Trade Name (controlled under 21 CFR 209.10(b)(1))

Example
Example DI: 01234567891011_DIT^^99ELR

Example Trade Name:
SARS-CoV-2 Test_Company_MNT^^99ELR

HL7 Field
OBX-17
OBX-18

Sequence ID

Required Reporting
Federal / CDC / HHS
State / Local / Tribal / Territorial PHD

Requested Reporting
N/A

Technical Specifications
Lab assigned Sequence ID – this is the ID used by the lab to upload the sequencing data to the national repositories (e.g., GISAID, NCBI Gene Bank) and will be useful in retrieving more data about the variant from those repositories as it will be incorporated into the virus name for the sequence.

Notes
Add as an additional observation to the original report

Example
LOINC: 98062-3 Sequencing study identifierAllowable = PLT2397^Filler Lab Assigned Genetic Sequence Identifier^PLTOBX-2 = ST**HL7 Field**
OBX-3
OBX-2
OBX-5

Performing Facility Name: CLIA#

Reporting – If Known
Federal / CDC / HHS
State / Local / Tribal / Territorial PHD

Requested Reporting
N/A

Technical Specifications
Alpha; ##D#######

Notes
CLIA Laboratory Search

Example
Example: 21D1234567

HL7 Field
OBX-23.10

*Note: Follow all applicable CLIA and FDA regulations when reporting sequencing results to an ordering provider.

Acronyms

Acronyms:

CDC: Centers for Disease Control and Prevention

CFR: Code of Federal Regulations

CLIA: Clinical Laboratory Improvement Amendments

CMS: Centers for Medicare and Medicaid Services

CX: Extended Composite ID

DI: Device Identifier

EHR: Electronic Health Record

EUA: Emergency Use Authorization

FDA: U.S. Food & Drug Administration

GISAID: Global Influenza Surveillance AID

GUDID: Global Unique Device Identification Database

HHS: Department of Health and Human Services

HL7: Health-Level Seven

ID: Identifier

LOINC: Logical Observations Identifiers Names and Codes

NAAT: Nucleic Acid Amplification Test

NCBI: National Center for Biotechnology Information

OBX: Observation/Result Segment

PHD: Public Health Department

RT-PCR: Reverse Transcription Polymerase Chain Reaction

SNOMED CT: Systemized Nomenclature of Medicine – Clinical Terms

ST: Structured Text

UDI: Universal Device Identification

Reporting Scenarios

Below are scenarios that provide examples of how to report SARS-CoV-2 sequencing results to public health departments. The first two examples are the preferred methods, and the third is an alternative method. Specific details for each example can be found on Confluence .

Preferred scenario (1): Send the sequencing results/SARS-CoV-2 lineage with the original (RT-PCR) or NAAT result that led to the decision to perform sequencing, if performed at the same laboratory or facility (parent-child test result linkage, if possible)

Preferred scenario (2): Send the sequencing results/SARS-CoV-2 lineage with the original RT-PCR or NAAT result that resulted in the decision to perform sequencing, if performed at the same laboratory or facility (no parent-child test result linkage)

Alternative scenario: Send only the sequencing results/SARS-CoV-2 Lineage as a new report with reference to the laboratory generated sequence ID (sent as a ST datatype, if CX (HL-7 datatype) is not possible)

Previous Updates

Updates from Previous Content

Updates as of June 15, 2021

- Provides clarification on how laboratories may report sequencing results to patients and providers in compliance with CLIA.
- Addition of 96895-8 as the preferred LOINC code to report sequencing results by molecular genetic methods and 98062-3 as the preferred code to identify sequencing studies.

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